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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,890	02/07/2002	John V. Frangioni	BIDM-P01-004	8688

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ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/071,890

Examiner

Hector M Reyes

Applicant(s)

FRANGIONI, JOHN V.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 to 66 is/are pending in the application.
- 4a) Of the above claim(s) 1 to 16, 18 to 20 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☒ Claim(s) 21 to 65 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 6. 6) ☐ Other: .

DETAILED ACTION

Paper Entry

Examiner acknowledges Applicant's:

- Information Disclosure Statement, filed on November 11 2002 as Paper no. 4,
- Information Disclosure Statement filed on February 2, 2003 as Paper no. 6,
- Request for Extension of Time filed on April 16, 2003 as Paper no. 7
- Response, filed on April 16, 2003 as Paper no. 8.

Applicant's election with traverse of Group VI, claims 17 and 21 to 65 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that:

- Compounds described in each particular group share a common structural feature with some differences that only one search based upon the common feature is needed.

This is not found persuasive because:

- Each group contain already a quite general chemical structure with its own limitations and embracing a large number of compounds and
- Each one of the said "general structure requires indeed a particular search and
- A given reference anticipating or suggesting one of the said general formulas cannot be used to reject any of the others groups within the meaning of 35 USC 102 and 35 USC 103, respectively.

The requirement is still deemed proper and is therefore made FINAL.

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The Examiner would like to point out for the record that on April 30, 2003, as described in the instant Interview Summary, the Examiner phoned Mr. Yu Lu in order to let him known that claim 11, claiming compound IC and any other claim depending from the said claim 11 form an additional group, which should be part of the series of groups presented on the Restriction Requirement, Paper no. 5. The missing group was not discussed in the Response, Paper no. 8. The Examiner offered Applicants the opportunity to present a new Restriction containing the said missing group. However, Applicant indicated that even having the additional group as an alternative, the selection of the group VI was maintained and that in order to advance the prosecution, and considering all possible groups, the elected group was the same: Group VI, containing claims 17, and 21 to 65. ***The present Examination is directed to the said elected set of claims wherein claims 21 to 65 are examined to the extend of the compounds of formula II as described in claim 17.***

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The phrase "general formula" is indefinite because the said formula is directed to a specific and defined number of compounds and therefore the said formula is not *general* since it is specific. The Examiner suggests the elimination of the word general.

Regarding the formula itself, it is not clear if the carbon atom enclosed in parenthesis has an additional hydrogen atom as a substituent or on the contrary should be substituted with any other organic moiety. Is the said $-(CH)-$ unit intended to represent a methylene unit $-(CH_2)-$?

The phrases – *chelate ligand*, *fluoresce tag* and *cytotoxic moiety*- are indefinite because it is not clear which specific organic groups or moiety would satisfy the intended limitations. What organic groups would be considered within the bounds or inside the classification of the said three groups? Examiner suggests the incorporation of the said moieties corresponding to each one of the said groups. For examination purpose, any possible moiety having general characteristic would be considered to satisfy the limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by:

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- Valiaeva et al J. Organic Chemistry, 2001, vol. 66 pages 5146-5154 or
- Tokutake et al, Bioorganic & Medicinal Chemistry, vol. 6, no. 10 pages 1935-1953 (1998) or
- Katoh et al, Bioorganic & Medicinal Chemistry, vol. 6 no 13, pages 1437-1442 (1996).

Valiaeva discloses a series of pseudopeptides analogues useful in the inhibition of Folylpolgamma glutamate synthetase. Among such derivatives see compounds of formula I, page 5148 and 5151.

Tokutake discloses the synthesis and Evaluation of transition states analogue Inhibitors of E. coli gamma glutamylcysteine Synthetase. Among the compounds discloses, see compounds 1 and 2, page 1936.

Katoh et al discloses analogues inhibitors of E. coli gamma glutamylcysteine Synthetase. Among the said derivative, see compound 1, page 1437 and compound 8, page 1438.

Claims Objections

Claims 21 through 65, hereby examined to extend of compound described in claim 17, are objected because the said claims depend, directly or indirectly from rejected claim 17.

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CONCLUSION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- WO 98/130046 Slusher et al
- US patent 6071965, Jackson et al
- US patent 5804602, Slusher et al
- US patent 6384022 B1, Jackson et al
- US patent 6444657 B1, Slusher et al

The above prior art disclose derivatives useful as NAALADase and different medical conditions. General description of the said derivatives is presented in a genus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on M-F 9 to 4 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 or (for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Héctor M. Reyes, Ph D JD

June 2, 2003


ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600